Effective 5/10/2016

Part 9
Charitable Prescription Drug Recycling Act

58-17b-901 Title.

This part is known as the "Charitable Prescription Drug Recycling Act."

Enacted by Chapter 405, 2016 General Session

58-17b-902 Definitions.

As used in this part:

(1) "Assisted living facility" means the same as that term is defined in Section 26B-2-201.

(2) "Cancer drug" means a drug that controls or kills neoplastic cells and includes a drug used in chemotherapy to destroy cancer cells.

(3) "Charitable clinic" means a charitable nonprofit corporation that:

(a) holds a valid exemption from federal income taxation issued under Section 501(a), Internal Revenue Code;

(b) is exempt from federal income taxation under Section 501(c)(3), Internal Revenue Code;

(c) provides, on an outpatient basis, for a period of less than 24 consecutive hours, to an individual not residing or confined at a facility owned or operated by the charitable nonprofit corporation:

(i) advice;

(ii) counseling;

(iii) diagnosis;

(iv) treatment;

(v) surgery; or

(vi) care or services relating to the preservation or maintenance of health; and

(d) has a licensed outpatient pharmacy.

(4) "Charitable pharmacy" means an eligible pharmacy that is operated by a charitable clinic.

(5) "County health department" means the same as that term is defined in Section 26A-1-102.

(6) "Donated prescription drug" means a prescription drug that an eligible donor or individual donates to an eligible pharmacy under the program.

(7) "Eligible donor" means a donor that donates a prescription drug from within the state and is:

(a) a nursing care facility;

(b) an assisted living facility;

(c) a licensed intermediate care facility for people with an intellectual disability;

(d) a manufacturer;

(e) a pharmaceutical wholesale distributor;

(f) an eligible pharmacy; or

(g) a physician's office.

(8) "Eligible pharmacy" means a pharmacy that:

(a) is registered by the division as eligible to participate in the program; and

(b)

(i) is licensed in the state as a Class A retail pharmacy; or

(ii) is operated by:

(A) a county;

(B) a county health department;

(C) a pharmacy under contract with a county health department;
(D) the Department of Health and Human Services created in Section 26B-1-201; or
(E) a charitable clinic.

(9)
(a) "Eligible prescription drug" means a prescription drug, described in Section 58-17b-904, that is not:
(i) except as provided in Subsection (9)(b), a controlled substance; or
(ii) a drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.
(b) "Eligible prescription drug" includes a medication-assisted treatment drug that may be accepted, transferred, and dispensed under the program in accordance with federal law.

(10) "Licensed intermediate care facility for people with an intellectual disability" means the same as that term is defined in Section 58-17b-503.

(11) "Medically indigent individual" means an individual who:
(a)
(i) does not have health insurance; and
(ii) lacks reasonable means to purchase prescribed medications; or
(b)
(i) has health insurance; and
(ii) lacks reasonable means to pay the insured's portion of the cost of the prescribed medications.

(12) "Medication-assisted treatment drug" means buprenorphine prescribed to treat substance use withdrawal symptoms or an opiate use disorder.

(13) "Nursing care facility" means the same as that term is defined in Section 26B-2-201.

(14) "Physician's office" means a fixed medical facility that:
(a) is staffed by a physician, physician's assistant, nurse practitioner, or registered nurse, licensed under this title; and
(b) treats an individual who presents at, or is transported to, the facility.

(15) "Program" means the Charitable Prescription Drug Recycling Program created in Section 58-17b-903.

(16) "Unit pack" means the same as that term is defined in Section 58-17b-503.

(17) "Unlawful conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-501.

(18) "Unprofessional conduct" means the same as that term is defined in Sections 58-1-501 and 58-17b-502.

Amended by Chapter 329, 2023 General Session

58-17b-903 Charitable Prescription Drug Recycling Program -- Creation -- Requirements.

(1) There is created the Charitable Prescription Drug Recycling Program.

(2) The division, in consultation with the board, shall:
(a) implement the program, on a statewide basis, to permit:
(i) an individual or an eligible donor to transfer an eligible prescription drug to an eligible pharmacy for dispensing to a medically indigent individual; and
(ii) an individual to transfer an eligible prescription drug to a physician's office:
(A) that is an eligible donor; and
(B) for transfer to an eligible pharmacy for dispensing to a medically indigent individual;

(b) in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, make rules necessary to implement the program; and
(c) provide technical assistance to entities that desire to participate in the program.

Amended by Chapter 397, 2021 General Session

58-17b-904 Criteria for eligible prescription drugs.

An eligible pharmacy may not accept or dispense an unused prescription drug under the program unless the unused prescription drug:
(1)
(a) is in a unit pack or the manufacturer's sealed container; or
(b) is an injectable medication;
(2)
(a) is unopened; or
(b) is a cancer drug packaged in an unopened single-unit dose that has been removed from a multi-dose package;
(3) is accepted and dispensed by the eligible pharmacy before:
(a) a beyond use date that appears on the label;
(b) the expiration date recommended by the manufacturer; or
(c) a date, established by division rule for a specific prescription drug, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, that is later than the date in Subsection (3)(a) or (3)(b);
(4)
(a) is not adulterated or mislabeled; and
(b) the pharmacist or licensed pharmacist technician accepting or dispensing the prescription drug does not have reason to believe that the prescription drug is adulterated or mislabeled.

Enacted by Chapter 405, 2016 General Session

58-17b-905 Participation in program -- Requirements -- Fees.

(1) An eligible donor, an individual, or an eligible pharmacy may participate in the program.
(2) An eligible pharmacy:
(a) shall comply with all applicable federal and state laws related to the storage, disposal, and distribution of a prescription drug;
(b) shall comply with all applicable federal and state laws related to the acceptance and transfer of a prescription drug, including 21 U.S.C. Chapter 9, Subchapter V, Part H, Pharmaceutical Distribution Supply Chain;
(c) shall, before accepting or dispensing a prescription drug under the program, inspect each prescription drug to determine whether the prescription drug is an eligible prescription drug;
(d) may dispense an eligible prescription drug to a medically indigent individual who:
(i) is located in the state when the drug is dispensed; and
(ii) has a prescription issued by a practitioner;
(e) may charge a handling fee, adopted by the division under Section 63J-1-504; and
(f) may not accept, transfer, or dispense a prescription drug in violation of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. Sec. 301 et seq.

Amended by Chapter 253, 2022 General Session

58-17b-906 Liability of participating organizations and manufacturers.

In the absence of bad faith or gross negligence, a person is not criminally or civilly liable for injury, death, or loss of property based solely on the fact that the person manufactured, provided, donated, accepted, or dispensed an eligible prescription drug under this part.

Enacted by Chapter 405, 2016 General Session

58-17b-907 Rules made by the division.

The rules made by the division under Subsection 58-17b-903(2)(b) shall include:

(1) registration requirements to establish the eligibility of a pharmacy to participate in the program;

(2) a formulary that includes all eligible prescription drugs approved by the federal Food and Drug Administration;

(3) standards and procedures for:

(a) verifying whether a pharmacy or pharmacist participating in the program is licensed and in good standing with the board;

(b) handling of an eligible prescription drug transferred in accordance with Subsection 58-17b-903(2) to an eligible pharmacy or a physician's office, including:

(i) acceptance;

(ii) identification, including redundant criteria for verification;

(iii) documentation, under 21 U.S.C. Sec. 360eee-1, of transaction information, history, and statements;

(iv) safe storage;

(v) security;

(vi) inspection;

(vii) transfer; and

(viii) dispensing;

(c) a pharmacist, pharmacy intern, or licensed pharmacy technician:

(i) working in or consulting with a participating eligible donor; or

(ii) assisting an individual donating the eligible prescription drug;

(d) disposition of a donated prescription drug that is a controlled substance;

(e) record keeping regarding:

(i) the individual or eligible donor that transferred an eligible prescription drug under Subsection 58-17b-903(2)(a);

(ii) the identification and evaluation of a donated prescription drug by a pharmacist or licensed pharmacy technician; and

(iii) the dispensing or disposition of a prescription drug;

(f) determining the status of a medically indigent individual;

(g) labeling requirements to:

(i) ensure compliance with patient privacy laws relating to:

(A) an individual who receives an eligible prescription drug; and

(B) patient information that may appear on a donated prescription drug;

(ii) clearly identify an eligible prescription drug dispensed under the program; and

(iii) communicate necessary information regarding the manufacturer's recommended expiration date or the beyond use date; and

(h) ensuring compliance with the requirements of this part;

(4) a process for seeking input from the Department of Health and Human Services created in Section 26B-1-201 to:

(a) establish program standards and procedures for assisted living facilities and nursing care facilities; and
(b) establish program standards and procedures for mental health and substance abuse clients; and
(5) the creation of a special training program that a pharmacist and a licensed pharmacy technician at an eligible pharmacy must complete before participating in the program.

Amended by Chapter 255, 2022 General Session